Cancer Research UK response to MHRA consultation on revision of European legislation on in vitro diagnostic medical devices

March 2013

Cancer Research UK (CR-UK) welcomes the opportunity to respond to the MHRA on the revision of European legislation on in vitro diagnostic medical devices (IVDs).

We broadly support the European Commission’s proposals for new regulations on IVDs and welcome the intention to provide greater consistency in standards across the EU. However, we share the MHRA’s concerns about proposed changes to the ‘in-house’ exemption for IVDs, as set out below. We also wish to emphasise the importance of maintaining the ‘in-house’ exemption for genetic tests.

The ‘in-house’ exemption – genetic tests and companion diagnostics

CR-UK is the largest independent funder of cancer research in Europe. Cancer Research UK is currently leading a national stratified medicine programme, which aims to improve genetic testing of tumours for cancer patients in the UK. The programme is a significant step towards making targeted therapies available for people with cancer in the UK, and is also capturing genetic data to inform future research. As such, the development and use of IVDs is essential to a significant part of our work.

We are therefore pleased that the current ‘in-house’ exemption for IVDs has been maintained for low and medium risk IVDS (class A, B and C IVDs under the new risk classification), including genetic tests and companion diagnostics. This exemption is essential to ensure the continuing availability of many genetic tests, particularly tests for ‘family-specific’ genetic mutations or for rare disorders (for which there are often no CE-marked kits available). It is also vital for research and treatment in the area of stratified medicines. Without this exemption, research costs could increase significantly and threaten the future of non-commercial research in this area.

We also welcome the introduction of a risk-based classification system for IVDs, which we think could help to ensure that the legislation is able to cover unforeseen future developments. Similarly, we support the obligation on health institutions developing ‘in-house’ tests for class A, B and C IVDs to be accredited according to the ISO 15189 standard or equivalent, as this should facilitate standardisation and improve safety for patients.

The ‘in-house’ exemption – high risk devices

While we welcome the ‘in-house’ exemption of class A, B and C devices, we share the MHRA’s concerns about the exclusion of class D ‘high-risk’ devices from this exemption (as outlined in Question 11 of the consultation). We support the European Commission’s aim to improve patient safety across the EU, but we are concerned that this would not be achieved by subjecting class D devices to the requirements of the IVD regulation. A formal accreditation process for health institutions would be a preferable approach, as this process would not just assess the test, but the whole diagnostic process, including the way that results are interpreted.

The removal of the ‘in-house’ exemption for class D devices could also result in significant costs, in both time and monetary terms, for the NHS and related UK bodies. A potential implication of this change may be:
Tests for the viruses which cause cervical cancer (e.g. HPV), a transmissible agent that causes a life-threatening disease with a high risk of propagation, are at risk of not being available to patients, because of overheads in time and expense needed for them to be CE-marked.

We therefore support the MHRA’s call for the ‘in-house’ exemption to apply to all IVDs, providing that the devices are developed by accredited health institutions. We also suggest greater clarity be sought with regard to what harmonisation in medical laboratory accreditation standards across the EU should look like.

We thank you again for the opportunity to respond to this consultation and look forward to ongoing dialogue with the MHRA on this issue. If you have any queries about this response please contact Hilary Tovey, Senior Policy Manager (hilary.tovey@cancer.org.uk; +44 (0)20 3469 8362).

About Cancer Research UK
Every year around 300,000 people are diagnosed with cancer in the UK. Every year more than 150,000 people die from cancer. Cancer Research UK is the world’s leading cancer charity dedicated to saving lives through research. Together with our partners and supporters, Cancer Research UK’s vision is to bring forward the day when all cancers are cured. We support research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses. In 2011/12 we spent £332 million on research. The charity’s pioneering work has been at the heart of the progress that has already seen survival rates in the UK double in the last forty years. We receive no government funding for our research.